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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,421	07/30/2001	Akira Suyama	01450/HG	6390

1933 7590 05/31/2002

FRISHAUF, HOLTZ, GOODMAN & CHICK, PC  
767 THIRD AVENUE  
25TH FLOOR  
NEW YORK, NY 10017-2023

EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/918,421

Applicant(s)

SUYAMA, AKIRA

Examiner

Channing S. Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2002, Paper No. 5.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 1 Sheet 6) ☐ Other:

## DETAILED ACTION

### *APPLICANTS' ELECTION*

Applicants' election with traverse of the first specie II (claims 1-11; screening oligo nucleic acids by a computer-based method) and the second specie VI (claim 6; n is 7) filed 11 March 2002, in Paper No. 5, is acknowledged. The traversal is on the grounds that the restriction/species requirement is not of the type set forth in the third paragraph of M.P.E.P. § 803.02. This is not found unpersuasive because M.P.E.P. § 808.01(a) (Column 2, entitled Species) states:

"Where there is no disclosure of relationship between species (see M.P.E.P. 806.04(b)), they are independent inventions and election of one invention following a requirement for restriction is mandatory even though applicant disagrees with the examiner. There must be a patentable difference with between the species as claimed. See M.P.E.P. 806.04(h). Since the claims are directed to independent inventions, restriction is proper pursuant to 35 U.S.C. 121, and it is not necessary to show a separate status in the art or separate classification.

A single disclosed species must be elected as a prerequisite to applying the provisions of 37 C.F.R. 1.141 to additional species if a generic claim is allowed.

Even if the examiner rejects the generic claims, and even if the applicant cancels the same and admits that the genus is unpatentable, where there is a relationship disclosed between species, such disclosed relation must be discussed and reasons advanced leading to the conclusion that the disclosed relation does not prevent restriction, in order to establish the propriety of restriction."

Further, M.P.E.P. § 808.01(a) p 800-47 (Column 2, last paragraph) to 800-48 (Column 1):

"Election of species should be required prior to a search on the merits (A) in all applications containing claims to a plurality of species with no generic claims, and (B) in all applications containing both species claims and generic or Markush claims."

Applicants are directed to the previous office action mailed 3 December 2001, Paper No. 3, which clearly indicates the basis for the patentably distinctness of the species, establishing a separate status in the art and a different field of search. Claim 12 is withdrawn from consideration as not directed to the elected group and/or species. It is noted that upon the allowance of a generic claim, applicants' will be entitled to consideration of claims to additional

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species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141.

The requirement is still deemed proper and is therefore made FINAL.

*CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-11.

**Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*VAGUE AND INDEFINITE*

Claim 1 (line 9) and all claims dependent therefrom recites the phrase “low frequency” implying a criteria of selection. Applicant can resolve this issue by particularly pointing out degree of frequency is chosen: 1. limited to requiring some size/range or 2. inclusive of random arbitrary frequency. The implied criterion is critical in applying it to the degree of frequency, and therefore it is unclear. Clarification is required via clearer claim wording.

Claims 2 (line 3) and 11 (dependent from claim 2) recites the phrase “different processes” which is vague and indefinite. Applicants can resolve this issue by particularly pointing out how or the type of “different processes” being referred to. The “different processes” are vague and indefinite, therefore, clarification is required via clearer claim wording.

Claims 6 (lines 22-23) and 11 (dependent from claim 6) recites the phrase “low occurrence frequency” implying a criteria of selection. Applicant can resolve this issue by particularly pointing out degree of frequency is chosen: 1. limited to requiring some size/range or 2. inclusive of random arbitrary frequency. The implied criterion is critical in applying it to the degree of frequency, and therefore it is unclear. Clarification is required via clearer claim wording.

Claims 8 (line 3) and 11 (dependent from claim 8) recites the phrase “ low stability” implying a criteria of selection. Applicant can resolve this issue by particularly pointing out degree of stability is chosen: 1. limited to requiring some size/range or 2. inclusive of random arbitrary stability. The implied criterion is critical in applying it to the degree of stability, and therefore it is unclear. Clarification is required via clearer claim wording.

Claims 9 (line 2) and 11 (dependent from claim 9) recites the phrase “a magnitude” implying a criteria of selection. Applicant can resolve this issue by particularly pointing out degree of magnitude is chosen: 1. limited to requiring some size/range or 2. inclusive of random arbitrary magnitude. The implied criterion is critical in applying it to the degree of magnitude, and therefore it is unclear. Clarification is required via clearer claim wording.

#### **Claims Rejected Under 35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, and 11 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Griffais et al.

Griffais et al. describes a method and computer program which allows the direct selection of highly specific amplification targets in a gene (human) and infectious agents based on K-tuple (overlapping sequences of defined length, K) frequency occurrences/disparity (Abstract and page 3887, first column, lines 33-36 of the INTRODUCTION section). The occurrence frequency of all possible base combinations in short sub sequences (K-tuple) is computed and identifies the most and least frequent sequences occurring in the databases (page 3887, first column, lines 20-23 of the INTRODUCTION section). The computer program employs three steps to define the target sequence to be amplified by PCR: 1) a first algorithm step is utilized to locate rare K-tuples, where  $K = 7$ , frequency  $\leq 0.52 \times 10^{-4}$ , therefore  $4^7$  possible heptamers (16,384); 2) potential targets are chosen according to size and the number of contiguous GC stretches in the fragment to be amplified; and 3) the sequence of the primers is identified, where the 3' end is the rare K-tuple (page 3887, second column, lines 6-16 of the MATERIAL AND METHODS section). Griffais et al. illustrates primer sequences identified, by the above method, for infectious agents and corresponding rare K-tuple locations (Table 1, note the underlined 7-tuple(s)). Three criteria are specified for selection of a target to be detected: 1) the target be flanked by rare heptamers (7-tuples); 2) the distance separating the rare patterns is included in a defined and variable range; and 3) the target not have 7 contiguous GCs, to prevent yield reduction due to secondary structures/stability as in instant claims 3, 5, and 8 (page 3890, second column, lines 5-12 of the APPLICATION section). Thus, Griffais et al. clearly anticipates the claimed invention.

Claims 1-5 and 8-11 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Rychlik et al.

Rychlik et al. describes a method and computer program (OLIGO) for choosing optimal oligonucleotides as probes for hybridization, primers for sequencing, or primer for DNA amplification (page 8543, lines 2-3 of the ABSTRACT section; page 8550, lines 24-29 of the DISCUSSION section). The authors state that three factors are considered when determining the quality of a probe: 1) stability of the duplex formed between the probe and target nucleic acid; 2) specificity of the probe for the intended target sequence; and 3) self-complementarity/intramolecular secondary structure (page 8543, lines 3-5 of the ABSTRACT section). OLIGO utilizes an algorithm to compute the duplex dissociation temperature ( $T_d$ ) based on nearest neighbor thermodynamic parameters, and results in the determination of self-complementarity of the oligonucleotides, the presence of palindromes in the nucleic acid sequence, and the presence of alternative (non-target) sites for the oligonucleotides within the nucleic acid sequence (page 8543 and 8544, lines 35-36 and 8-13 of the INTRODUCTION section, respectively; and equation (ii)). Further, OLIGO calculates  $T_m$  (melting temperature) (page 8545, line 15 of the METHODS section). Probe specificity and secondary structure is determined by checking the entire nucleic acid sequence for possible formation of stable duplexes with a given oligonucleotides (page 8549, lines 19-23 of the RESULTS section). The authors utilize OLIGO to compare oligonucleotide 6 to oligonucleotide 10 and identify 7-nucleotide/tuple duplexes as illustrated in Figure 3 (page 8549, lines 23-29 of the RESULTS section). Thus, Rychlik et al. clearly anticipates the claimed invention.

**No Claims Are Allowed**

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CMI Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *May 29, 2002*

Examiner Initials: *CSM*

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER